

**TESTIMONY OF
MARK McCLELLAN, MD, Ph.D.
ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING
HEARING ON
THE TRANSITION OF FULL-BENEFIT DUAL ELIGIBLE BENEFICIARIES TO THE
MEDICARE PRESCRIPTION DRUG BENEFIT**

March 3, 2005

Chairman Smith, Senator Kohl, distinguished members of the Committee, thank you for inviting me to discuss the transition of full-benefit dual eligible Medicaid beneficiaries to the new Medicare prescription drug benefit.

Beginning in 2006, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) makes prescription drug coverage available to all 43 million Medicare beneficiaries. This important new benefit will provide beneficiaries with substantial help in paying for their prescription drugs, greatly enhancing their quality of life. The law also gives Medicare the ability, for the first time in the program's 40-year history, to provide additional comprehensive help to those in greatest need – beneficiaries with very high prescription drug costs and people with low incomes. Under the MMA, millions will receive comprehensive prescription drug coverage at little or no cost.

All Medicare beneficiaries will have the opportunity to participate in the new prescription drug benefit, including the approximately six-million low-income beneficiaries who also are enrolled in Medicaid. Known as “full-benefit dual eligibles,” these beneficiaries will qualify for Medicare (instead of Medicaid) prescription drug coverage with low or no premiums and co-payments of a few dollars. CMS recognizes the enormity of the transition from Medicaid drug coverage to Medicare and is working diligently to ensure the process for beneficiaries is as quick and efficient as possible. Most importantly, protections are in place to help ensure that no full-benefit dual eligible beneficiary will go without coverage when the new Medicare prescription drug benefit starts on January 1, 2006. This is critically important, especially for beneficiaries with chronic conditions who take a number of prescriptions. In addition, CMS will pay particular attention to the formulary designs of the new drug plans to ensure they are not

discriminatory and they meet the needs of all beneficiaries. CMS will ensure formularies recognize the special needs of beneficiaries, including those with disabilities, mental health illness, HIV/AIDS, and those who live in nursing homes.

Standard Benefit Includes Protection from High Drug Costs

The new Medicare prescription drug benefit will offer protection from high pharmaceutical costs for all beneficiaries, regardless of income. Under the standard drug benefit, Medicare will cover on average 75 percent of a beneficiary's drug expenses up to \$2,250, after a \$250 deductible. Once a beneficiary's out-of-pocket spending reaches \$3,600 in a year, the drug benefit will cover about 95 percent of any additional pharmaceutical expenses, effectively protecting the beneficiary from very high drug costs. There is no cap to the Medicare coverage so beneficiaries will be continuously covered after reaching the out-of-pocket spending limit.

Additional Benefits for Low-Income Beneficiaries

The new drug benefit provides even greater protection for low-income and full-benefit dual eligible beneficiaries through a low-income subsidy. Qualification for the low-income subsidies will vary based on the status of the beneficiary (See Attachment 1).

Full-Benefit Dual Eligible Beneficiaries

Full-benefit dual eligible beneficiaries - those who currently receive full Medicaid benefits - will automatically qualify for the low-income subsidy. For beneficiaries in this category with incomes of 100 percent or less of the Federal Poverty Level (FPL), the Federal government will pay for their premiums up to the benchmark amount, and their entire deductible. The beneficiaries will only be responsible for nominal co-payments of no more than \$1 for generic or preferred drugs or \$3 for other drugs and, should they select such a plan, any premium amount exceeding the benchmark premium until the out-of-pocket limit is reached. As a result, Medicare will pay on average 98 percent of these beneficiaries' drug costs.

Full-benefit dual eligible beneficiaries with incomes greater than 100 percent of the FPL will not pay premiums up to the benchmark amount or deductibles and will have co-payments of no more than \$2 for generic or preferred drugs or \$5 for other drugs.

The new law offers even greater protection for the approximately 1.5 million full-benefit dual eligible beneficiaries who reside in institutions. They will pay no premiums, no deductibles, no coinsurance, no co-payments, and will not have to spend their personal needs allowance on prescription drugs.

Medicare Savings Program and Social Security Income Beneficiaries

Low-income Medicare beneficiaries who are enrolled in a Medicare Savings Programs (QMB, SLMB, and QI programs) or who receive Supplemental Security Income (SSI), will automatically qualify for a low-income subsidy. The Federal government will pay for the entire deductible and premiums up to the benchmark amount for beneficiaries enrolled in a Medicare Savings Program. These beneficiaries will have co-payments of \$2 generic or preferred drugs or \$5 for other drugs until the out-of-pocket limit is reached. If they select a plan with a premium that exceeds the benchmark amount, they will be responsible for the difference. Subsidies vary for SSI recipients depending on whether or not the beneficiary has Medicaid coverage. SSI recipients with Medicaid coverage will have no premiums or deductibles and will have co-payments of no more than \$1 for generic or preferred drugs and \$3 for other prescriptions until the out-of-pocket limit is reached. SSI recipients without Medicaid coverage will have no premiums or deductibles and will have co-payments of no more than \$2 for generic or preferred drugs or \$5 for other drugs until the out-of-pocket limit is reached.

Other Low-Income Beneficiaries

Subsidies also are available to other Medicare beneficiaries with incomes less than 150 percent of the FPL. These beneficiaries must apply for the low-income subsidy, which varies based on income. Those with incomes less than 135 percent of the FPL and assets up to \$6,000 (or \$9,000 for a couple) in 2006 will pay no premium up to the benchmark or deductible and will have cost sharing of up to \$2 for generic drugs and preferred drugs \$5 other prescriptions up to the out-of-pocket limit of \$3,600, after which there will be no cost sharing.

Beneficiaries with incomes less than 135 percent of the FPL with assets between \$6,000 and \$10,000 (\$9,000 and \$20,000 for a couple) will have no premiums and a \$50 deductible. Cost sharing for such beneficiaries will not exceed 15 percent up to the out-of-pocket limit. There

will be no coverage gap and co-payments will be \$2 for generic or preferred drugs and \$5 for other drugs after the out-of-pocket limit has been reached. On average, Medicare will pay about 96 percent of the drug costs for beneficiaries with incomes below 135 percent of the FPL.

Subsidies also are available for beneficiaries with incomes greater than 135 percent, but less than 150 percent, of the FPL and assets up to \$10,000 (\$20,000 for couples) in 2006. Premiums for such beneficiaries will be based on a sliding income scale. The deductible will be \$50 and cost sharing will not exceed 15 percent coinsurance for costs up to the out-of-pocket threshold. Once the out-of-pocket threshold has been reached, beneficiaries in this income group will also have co-payments of up to \$2 generic and preferred drugs and \$5 other drugs. For beneficiaries in this income range, Medicare will cover an average of 85 percent of their drug costs. As mentioned above, beneficiaries who select a prescription drug plans with premiums that exceed the benchmark will be responsible for the difference.

The low-income subsidy available under the MMA will impact a large number of Medicare beneficiaries. In fact, in 2006, 14.4 million individuals will qualify to receive help at one level or another under the subsidy program, including:

- 6.3 million full-benefit dual eligible beneficiaries;
- 5.7 million beneficiaries with income under 135 percent of FPL who meet the lower asset tests (which number includes 2 million Medicare Savings Program beneficiaries); and
- 2.4 million beneficiaries with incomes below 150 percent of FPL who meet the higher asset test.

This means that approximately one-third of the nearly 43 million Medicare beneficiaries will be receiving substantial assistance with their drug costs. The remaining two-thirds also will have significant assistance with their prescription drug costs.

Planning the Transition from Medicaid to Medicare

Mr. Chairman, I understand that some Members of Congress are interested in hearing about the comprehensive plan CMS has put in place for full-benefit dual eligible beneficiaries to move from Medicaid to the new Medicare drug benefit on January 1, 2006. Along with our many partners in making sure that full-benefit dual eligibles get the most out of the new comprehensive Medicare benefit, we are implementing a comprehensive plan to assure there are no gaps in

coverage for these beneficiaries. CMS is currently working with states to establish data exchanges that will identify full-benefit dual eligible beneficiaries whose coverage under Medicaid will end on December 31, 2005. After identifying these beneficiaries, CMS will contact them by mail this summer to inform them that they are deemed eligible for the low-income subsidy. Information will also be available through 1-800 MEDICARE, www.medicare.gov and through state Medicaid offices. And this fall, the full-benefit dual eligible beneficiaries will be notified of the plan in which they will be auto-enrolled if they do not choose a plan beforehand.

CMS is engaged in multiple meetings and coordination efforts with the states to ensure a smooth transition process. We are currently drafting a "State Legislators' Checklist" in conjunction with state associations, which includes questions pertaining to the role states have for coordinating with State Pharmacy Assistance Programs (SPAPs), accepting and processing low-income subsidy applications, retiree options, state contributions, state insurance laws and regulations, as well as general education and awareness. The checklist will also provide instruction on how the transition of full-benefit dual eligibles will be handled.

CMS will have multiple opportunities to disseminate the checklist to the states. The National Conference of State Legislatures, Council of State Governors, state committee chairpersons and state legislators will each receive mailings. In addition, CMS Regional Offices will serve as an addition resource for states. CMS also is working with the National Governors' Association to convene meetings with state SPAP representatives and with each state Medicaid director. Monthly conference calls with state Medicaid directors are scheduled to provide an opportunity to work through any issues and ensure as much information as possible is available. Furthermore, the SPAP Workgroup is developing guidance on how to use the SPAP grants effectively and CMS will work with the State Issues Workgroup on further guidance on transition issues.

Working in conjunction with the states and Social Security Administration (SSA), CMS also will conduct expansive outreach activities in the spring of this year (which will be described later in this statement) to educate Medicare beneficiaries about the new prescription drug plan and to

encourage those who do not automatically qualify for the low-income subsidy to apply. To avoid confusion, CMS will notify full-benefit dual eligible beneficiaries, Medicare beneficiaries who receive SSI benefits, and those enrolled in an MSP that they automatically qualify for the subsidy and do not need to apply. To make the enrollment process as simple as possible for beneficiaries not deemed eligible for the low-income subsidy, CMS worked with SSA and many advocacy groups through an extensive public process to develop the application form and process to be used to verify a beneficiary's income and resources to qualify them for the low-income subsidy. SSA and state Medicaid agencies will be responsible for handling the low-income subsidy application process. Beneficiaries may apply online, by phone, mail, or in person, and no financial documents will be required at the time of the application. Information listed on the application will be verified later, and beneficiaries will only be asked for follow-up documentation if the application cannot be verified through data matches.

As I mentioned, in June CMS will notify full-benefit dual eligible beneficiaries that their Medicaid prescription drug coverage is ending and that they have the right to choose a new Medicare prescription drug plan. Full-benefit dual eligible beneficiaries will be automatically enrolled in a plan in the fall of 2005, once the plans become available. Beneficiaries will still have an opportunity to select and enroll in a plan on their own, but if they take no action, their enrollment in the CMS-selected plan will become effective January 1, 2006. This will ensure there is no gap in their prescription drug coverage. For those beneficiaries who do not enroll in a plan, a notification will provide the opportunity for them to choose another plan. When auto-enrolling a beneficiary, CMS will operate under the following set of guidelines to select an appropriate plan.

- Beneficiaries already enrolled in a Medicare Advantage plan will be enrolled in a Medicare Advantage Prescription Drug (MA-PD) plan within the same organization to ensure continuity of care. The specific plan selected within the organization will have the lowest premiums.
- Typically, all other beneficiaries will be auto-enrolled in prescription drug plans selected at random that have premiums that do not exceed the premium subsidy amount.

Auto-enrollment will begin monthly after the new Medicare prescription drug plans become available this fall for full-benefit dual eligible beneficiaries. These beneficiaries may switch to a different plan than the one in which they were auto-enrolled. And full-benefit dual eligible beneficiaries may switch plans at any time from one MA-PD to another, from one PD plan to another, or from traditional Medicare and a PD plan into a MA-PD and vice versa. This process ensures that all full-benefit dual eligible beneficiaries maintain a continuity of care with their prescription drug coverage when Medicaid prescription drug coverage ends, while retaining the right to select a plan that best meets their needs. Full-benefit dual eligible beneficiaries also may switch plans after the program begins January 1, 2006.

CMS will facilitate the enrollment for other low-income beneficiaries who receive the low-income subsidy, whether they apply or are deemed eligible. These beneficiaries will receive a letter notifying them they have until May 15, 2006, the end of the open enrollment period, to select a plan. If the beneficiaries do not select a plan, they will be enrolled in a plan effective June 1, 2006. Once enrolled, beneficiaries will have the opportunity to switch plans during a special enrollment period, which runs until the end of 2006.

Extensive Outreach and Education Planned

CMS is aware that education and outreach to beneficiaries about the new drug benefit is critical to its success. CMS will work with a broad array of partners including the Administration on Aging (AoA), our sister agency at HHS, to educate beneficiaries, their caregivers, and others who can help them make decisions about the new Medicare prescription drug benefit and other new Medicare benefits and options. SSA, other Federal agencies, states, employers, unions, and national and community-based organizations will all participate in this effort. Successfully reaching beneficiaries will provide them with the opportunity to select a plan that meets their needs. Mr. Chairman, CMS would welcome any assistance Members of Congress can provide. Participating in Town Hall meetings and including information in your newsletters would complement CMS' outreach activities.

CMS is working on an integrated and multi-pronged education effort that will include media advertising, simple language fact sheets, detailed publications including the annual "*Medicare &*

You" handbook, direct mail, and community-based grassroots efforts to target specific populations with messages directed to their specific needs, including low-income beneficiaries. CMS has enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). CMS increased SHIP funding in 2004 and will provide \$31.7 million to SHIPs in 2005, reflecting the increased emphasis on one-on-one advice and counseling for Medicare beneficiaries. The SHIPs are among the most effective resources in helping beneficiaries learn about the changes to Medicare and will use the additional funds to equip their local organizations with the tools needed to answer beneficiaries' questions.

Additionally, CMS is supporting non-profit community-based organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach. CMS is working with the Access to Benefits Coalition (ABC), a coalition of almost 100 beneficiary and patient support organizations to target this hard-to-reach population. CMS is gaining valuable experience working with these organizations on the Medicare-approved drug discount card program that will be useful for outreach and education and providing enrollment assistance, especially with the low-income population.

CMS also is conducting the Regional Education About Choices in Health (REACH) Campaign, a nationally coordinated educational and publicity effort implemented on the local level by CMS' 10 Regional Offices through their partners. The campaign will work with community organizations and ensure that low-income Medicare beneficiaries, including full-benefit dual eligible beneficiaries, who may not have learned about the new benefit and subsidy program because of barriers of location or literacy, know how and where to get their questions answered, receive culturally and linguistically appropriate information, and receive accurate and reliable information tailored to meet community needs.

CMS also will work with providers in the nursing home arena, pharmacies and other health professions to let them know how to further assist beneficiaries who they care for and interact with as well as those who can benefit from this important new Medicare resource. CMS is also working with Medicare Today, a partnership of nearly 100 major health care organizations, including providers, advocacy entities, plans and employers to inform beneficiaries about the

new drug benefit. Medicare Today will be a coast-to-coast grassroots effort utilizing the capacities of its various member organizations.

CMS has identified 21 specific Federal programs that employ 80 different communications resources that can be used to educate Medicare beneficiaries about the new drug benefit. For example, the national network of community aging services providers funded by AoA are an important component of our outreach efforts. As the largest provider of home and community-based care in the country, the 56 state agencies on aging, 655 area agencies on aging and 29,000 community providers interact with seniors, particularly low-income elderly, on a daily basis at meal sites, senior centers and in their homes. Other examples of how other Federal agencies can provide assistance include:

- The Department of Housing and Urban Development provides funding for more than 2,000 service coordinators around the country who interact with seniors on a daily basis. CMS is partnering with HUD and the American Association of Service Coordinators to educate HUD residents about the drug benefit.
- The Department of Agriculture's Rural Housing Service targets elderly, disabled, and low-income rural residents. CMS has begun discussions with them to explore ways that we can coordinate with RHS' work, so that the Medicare beneficiaries they interact with will be made aware of the existence of the drug benefit and how it can help them.
- The Department of Energy's Weatherization Assistance Program also targets low-income Americans, particularly households with elderly residents, disabilities or children. CMS has begun discussions with them as to how we can partner with them to contact Medicare beneficiaries about the drug benefit.

The goal is to leverage the resources of the Federal government in such a way that all departments and agencies that potentially interact with Medicare beneficiaries will provide either education materials themselves, or an avenue through which beneficiaries can learn more. The White House will be working with the Department of Health and Human Services and CMS to advocate this inter-departmental and inter-agency effort.

Protections for Beneficiaries

In addition to ensuring a smooth transition for full-benefit dual eligible beneficiaries, the new Medicare prescription drug benefit includes a number of protections. To ensure that drug plans

provide access to medically necessary treatments for all beneficiaries and do not discriminate against any beneficiaries, these protections include use of appropriate formularies; provisions for beneficiaries who reside in long term care facilities; coverage determination, exceptions, and appeals processes; privacy protections; customer service provisions; and enforcement actions. CMS will rely on widely recognized best practices for existing drug benefits that serve millions of seniors and people with disabilities in order to ensure uninterrupted access for Medicare beneficiaries. In addition, a Medicare Beneficiary Ombudsman will serve as a beneficiary advocate to ensure people with Medicare receive the benefits and right to which they are entitled. The Ombudsman will closely track all issues related to drug benefit access. CMS is nearing the end of its search process to fill the position.

Formularies Address Special Needs

The MMA requires each formulary to include at least two drugs in each approved category and class, unless only one drug is available for a particular category or class. This requirement, however, should be viewed as a minimum and plans are encouraged to include more in their formularies. CMS may require formularies to include more than two drugs per category or class in cases in which additional drugs offer unique and important therapeutic advantages and where their exclusion may substantially discourage beneficiaries with certain diseases from selecting the plan. This will ensure plans and formularies do not discriminate against a particular type of patient.

All plan formularies must be developed and reviewed by a pharmacy and therapeutics committee (P&T). A majority of the committee members must be practicing physicians or pharmacists and at least two members – one practicing physician and one practicing pharmacist – must have expertise in geriatric and disabled care. Plans' benefit management tools, such as prior authorization, will be compared to existing national drug benefit management standards and guidelines to ensure they are used in a clinically appropriate manner. The goal of this process is to make sure beneficiaries have access to medically necessary prescription drugs and to allow plans to design and manage their formularies to provide the most affordable benefit possible.

CMS intends to encourage and approve formularies that provide drug lists and benefit management approaches that are already in widespread use. In addition to determining that the categories, classes and the formulary list are not discriminatory, CMS intends to check the plan design, using clear benchmarks that plans can utilize as a guide in building formularies and structuring their bids.

Mr. Chairman, it is important to note that CMS will ensure when plans develop their formularies the plans recognize the special needs of particular types of beneficiaries, such as mental health patients, those with HIV/AIDS, those living in nursing homes, people with disabilities and other beneficiaries who are stabilized on certain drug regimens. CMS regulations require each plan to submit a transition plan for moving enrollees currently taking a Part D drug that is not on their formulary to a medication that is on the list. The process must address situations where a beneficiary seeks to fill a prescription that is not on a formulary, but is unaware of what is covered by the plan or what is included in the exception process. CMS will review these plans as part of the approval process and a plan will not be approved unless its transition plan is adequate to protect Medicare beneficiaries.

Medicare prescription drug plans must arrange with their pharmacy network to provide notices of beneficiary rights under Medicare coverage determination processes. The beneficiary may always pay in full for any prescription and initiate an exceptions request. If a beneficiary requests an exception, plans must make their decisions within 24 hours for expedited requests or sooner if the patient's health requires it. Should the exceptions request be upheld, the beneficiary may submit the receipt for the purchase and the plan will later reimburse the beneficiary for any plan liability. If the beneficiary cannot afford to purchase the entire prescription, pharmacies typically have procedures for dispensing a few doses of a prescribed drug (for which the beneficiary pays). The Medicare prescription drug plans must comply with the provisions of the Federal notice and guidelines, but they may establish additional contractual procedures with their pharmacy network to address such a situation. CMS currently is investigating what additional guidance may be provided to the prescription drug plans and the pharmacies.

Addressing the Needs of Long-Term Care Residents

CMS is working to make the transition from Medicaid to Medicare smooth for all full benefit dual eligible beneficiaries, and there will be specific protections for beneficiaries who live in long-term care facilities and get their prescriptions from long-term care pharmacies. As a condition of providing the new benefit, every plan must provide coverage to all its enrollees who live in any nursing home in its region. To help facilitate the transition, the Medicare prescription drug plans will be notified as to which of their enrollees live in a long-term care setting. This will help the plans and the facilities prepare for any potential changes to a beneficiary's drug regimen. As you know, Mr. Chairman, simultaneously changing a number of prescriptions could adversely affect the health of the patient. Because a large number of long-term care residents may be auto-enrolled, it is important for the transition process to account for filling the first prescription. Medicare prescription drug plans will need to ensure that long-term care pharmacies in their network work with long-term care facilities before enrollment begins to ensure a smooth transition. Also, plans may need to provide a temporary "fill first" supply order for a limited amount of prescribed medications. CMS expects plans' applications for participation in the Medicare prescription drug program to explain their proposed procedures and timeframes to transition beneficiaries who live in long-term care facilities to the new benefit.

Beneficiaries residing in long-term care facilities are more likely to have prescriptions for multiple medications. Fortunately, the MMA includes a new Medication Therapy Management benefit. As an additional clinical support service that will improve the quality of care delivered, beneficiaries enrolled in a new Medicare prescription drug plan that are considered "at risk" (those with costs exceeding \$4,000 annually, those with multiple co-morbidities, and those with taking multiple medications) will receive this service to optimize therapeutic outcomes through improved medication use.

Effective Decision Support through Information Technology in Nursing Homes

CMS also is working to improve the quality of care and delivery of prescription drugs at nursing homes across the country. CMS is changing the culture of nursing homes and helping them to incorporate computer technology into their daily operations by examining nursing home data collection and analysis practices, and through special projects and demonstration programs.

Regarding data collection, CMS sees opportunities to encourage nursing homes to adopt or upgrade their computer systems through the Minimum Data Set, the system in which nursing homes submit their claims data to the states. Once these data are collected, they are analyzed and reported on an electronic data network. These reports, which maintain patient confidentiality, are very useful for improving quality of care, but only nursing homes with access to basic computer systems can access them. CMS is conducting several projects to test how best to incorporate information technology into nursing homes. For example, under the “One-Touch” pilot program, hand-held devices are being tested in several nursing homes. Through these efforts, CMS is working to help nursing homes realize the potential information technology has to improve the quality of care delivered in long-term care settings.

State Savings and Wrap-Around Options

States will realize significant savings under the reforms made by the MMA, even after refunding some of their current Medicaid drug outlays to the Federal government and these savings can be used to provide further protections for Medicaid beneficiaries. Each state will see fiscal relief when all facets of the Medicare reforms are considered. For example, states will pay a declining portion of prescription drug costs for full-benefit dual eligible beneficiaries. In addition, states will receive assistance with their retiree prescription drug costs, further reducing their spending on prescription drugs. CMS also is prepared to assist states in implementing the new law to ensure they save the maximum amount possible. As part of this effort, CMS has established a number of state workgroups to provide detailed guidance on the transition and administrative issues facing the states, such as determining eligibility for the low-income subsidy and moving full-benefit dual eligible beneficiaries to the new Medicare drug benefit.

Under the MMA, states can use their savings to “wraparound” the Medicare program by continuing to cover certain excluded drugs that the Medicare prescription drug benefit will not cover. States also will receive Federal match for those drug costs. Under the law, states that cover excluded drugs for their non full-benefit dual eligible Medicaid population must provide this same coverage to those who are full-benefit dual eligible beneficiaries. This provision of the law is fair and equitable and is in the best interest of full-benefit dual eligible beneficiaries and Medicaid programs. States make reasonable decisions on coverage of these drugs that provide

good health care and are economical to the programs. This decision making process should not be any different for the disabled and elderly than it is for families and children.

States with State Pharmacy Assistance Programs also can wraparound the new Medicare prescription drug benefit with their programs. States that choose to do so will be able to provide the same or better coverage at a lower state cost per beneficiary. And Medicaid programs that cover the excluded drugs or provide a wraparound will receive the Federal match as well.

CMS is currently drafting a letter to state Medicaid Directors to provide them with information regarding the Federal match. The letter reminds the states that Federal match will not be available for Part D drugs in the Medicaid program for dual eligibles participating in the Medicare prescription drug program as of January 1, 2006. In addition, the letter informs the states that one option they may want to consider for Medicaid coverage is allowing dual eligibles to receive an extended supply (e.g., 60 or 90 days) of their prescriptions near the end of this calendar year, provided an extended supply is allowed in their approved state plan. To do so would give beneficiaries access to the medication they need to carry them into the first several weeks of the program without violating the Federal match provisions in the MMA.

The wraparound provisions will further protect beneficiaries. The Medicare prescription drug plans will cover drugs in categories that address serious medical conditions and will not deny coverage simply because a state covers a less expensive alternative. Medicare prescription drug plans also may choose to cover some excluded drugs and in such cases, the state Medicaid program would be secondary to the Medicare prescription drug plan. As you know, states will make contributions on a monthly basis to the Federal government for the cost of providing the drug benefit. This amount will decline over time. Drugs excluded from the new prescription drug program are specifically excluded from the contribution each state makes. As a result, states are not double charged if they cover such drugs for full-benefit dual eligible beneficiaries.

CMS also has made significant strides to minimize the impact of the administrative functions associated with eligibility determinations and enrollment procedures. First, along with the SSA, CMS is encouraging beneficiaries to apply for the low-income subsidy with SSA. Individuals will not even have to leave home to make such applications. We will provide guidance to states

that also encourages them to use the SSA eligibility determination process. In addition, when an individual asks to enroll at a state office, the costs associated with this application will be matched by the Federal government.

CMS has worked to be sure that the process for applying for the low-income subsidy has been as automated as possible to minimize the burden to states in making low-income subsidy eligibility decisions. Furthermore, we have made sure that the process for such determinations through the SSA is available to the states; so that they all have a uniform, electronic method available to them should they choose to use it.

We are working closely with the state issues workgroup to produce useful outreach and education materials packages that the states can use in their interactions with beneficiaries. CMS has also prepared language that states can use to mail to their own constituencies so that they don't have to write their own letters to beneficiaries explaining the functioning of the state entities with regard to the new drug benefit.

Coverage and Appeals Protections

To further protect enrollees, the new prescription drug benefit provides coverage determination provisions, including exceptions, and appeals processes for drugs that are not included on a plan's formulary. In order to best serve enrollees, there are short timeframes and simple procedures for plan decisions on coverage determinations. As a result, enrollees will quickly receive decisions about medically necessary drugs that are not covered by a plan's formulary. Generally, plans must make their decisions in no less than 24 hours for expedited requests. However, the decision may be quicker if the patient's health requires it. A plan must provide an expedited determination when it determines, or the enrollees' prescribing physician indicates, that applying the standard timeframe may seriously jeopardize the life or health of the enrollee or the enrollees' ability to regain maximum function. In addition, plans must notify affected enrollees of any changes to their formularies or cost-sharing levels at least 60 days in advance of the change taking effect. If a plan fails to provide such notice, it must provide affected enrollees with a 60-day supply of the medication in dispute and notice of the change when a refill is

requested. This 60-day notice requirement provides adequate time for enrollees to request an exception and file an appeal, if needed.

Each plan must have a procedure for making timely coverage determinations on standard and expedited requests made by enrollees. An enrollee or his or her appointed representative, such as a family member or physician, may request a coverage determination (which includes an exception) or an appeal. In addition, an enrollee's prescribing physician may request a coverage determination or an expedited redetermination on behalf of an enrollee without being the enrollee's appointed representative. Generally, plans must grant exceptions when they determine that it is medically appropriate to do so. Once an exception is approved, a plan may not require an enrollee to request approval for a refill for the remainder of the plan year so long as the physician continues to prescribe the drug and the drug continues to be safe and effective for treating the enrollee's condition. Should a plan make an unfavorable coverage determination, such as denying an exception request, the enrollee, or his or her appointed representative, may appeal the plan's decision to an external entity.

The appeals process for the new Medicare prescription drug benefit is modeled after the Medicare Advantage appeals process, which includes five levels of appeals. CMS and the prescription drug plans are required to provide a considerable amount of information to enrollees, caregivers, patient advocacy groups, providers, and the general public about the coverage determination and appeals processes. As mentioned previously, CMS will monitor plans and review enrollee complaints to ensure that plans do not engage in discriminatory practices. Enforcement actions will be taken against plans that violate Medicare's requirement.

Mr. Chairman, while the appeals process provides an important protection for enrollees, CMS does not expect it to be used frequently. In addition to comprehensive formularies and oversight to ensure benefits are nondiscriminatory, best practices from existing benefit packages will be used. Appeals are generally uncommon when such benefit packages are in place.

Privacy and Customer Service

Furthermore, the new Medicare prescription drug program guarantees privacy and includes customer service protections. Exchanges of data between agencies for purposes of determining and verifying eligibility are conducted in accordance with applicable law. Moreover, plans are required to maintain beneficiary privacy and confidentiality. Medicare will review complaints and take enforcement action against plans that do not meet the requirements of participating in the drug benefit. Medicare also will provide consistent information through 1-800-MEDICARE call centers, the Internet, and beneficiary assistance groups about drug coverage, beneficiary payments, and ways to save on prescription drug costs.

As you can see, the new Medicare prescription drug program includes a host of extensive protections that are available to all beneficiaries, along with additional options for those with low incomes. These protections will ensure that appropriate medicines are available when needed, especially for those with serious illnesses that require expensive prescription drugs.

Conclusion

Mr. Chairman, thank you for this opportunity to discuss the new Medicare prescription drug benefit and the transition process and protections for full-benefit dual eligible beneficiaries. The new benefit also provides a substantial subsidy for low-income beneficiaries, while maintaining their ability to select a plan that best address their needs. At the same time, CMS and its partners are working to ensure full benefit dual-eligibles do not experience any gaps in their coverage during the transition. I thank the Committee for its time and would welcome any questions you may have.

Attachment 1

For 2006, the premium and cost-sharing amounts for various subsidy eligible groups are as follows:

FPL & Assets	Percentage of Premium Subsidy Amount (1)	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible individual – institutionalized individual	100%*	\$0	\$0	\$0
Full-benefit dual eligible individual – Income at or below 100% FPL (non-institutionalized individual)	100%*	\$0	The lesser of: (1) an amount that does not exceed \$1-generic/preferred multiple source and \$3-other drugs, or (2) the amount charged to other individuals below 135% FPL and with assets that do not exceed \$6,000 (individuals) or \$9,000 (couples)	\$0
Full-benefit dual eligible individual – Income above 100% FPL (non-institutionalized individual)	100%*	\$0	An amount that does not exceed \$2-generic/preferred multiple source and \$5-other drugs	\$0
Other low-income beneficiary with income below 135% FPL and with assets that do not exceed \$6,000 (individuals) or \$9,000 (couples)	100%*	\$0	An amount that does not exceed \$2-generic/preferred multiple source and \$5-other drugs	\$0
Other low-income beneficiary with income below 135% FPL and with assets that exceed \$6,000 but do not exceed \$10,000 (individuals) or with assets that exceed \$9,000 but do not exceed \$20,000 (couples)	100%*	\$50	15% coinsurance	An amount that does not exceed \$2-generic/preferred multiple source drug or \$5-other drugs
Other low-income beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed \$10,000 (individuals) or \$20,000 (couples)	Sliding scale premium subsidy (100%-0%)	\$50	15% coinsurance	An amount that does not exceed \$2-generic/preferred multiple source drug or \$5-other drugs

(1) Premium subsidy amount as defined in §423.780(b)

*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.